Article - Health - General

[Previous][Next]

§2–803.

(a) The Maryland Medical Assistance Program may notify the Attorney General of any increase in the price of an essential off–patent or generic drug when:

(1) The price increase, by itself or in combination with other price increases:

(i) Would result in an increase of 50% or more in the wholesale acquisition cost of the drug within the preceding 1–year period; or

(ii) Would result in an increase of 50% or more in the price paid by the Maryland Medical Assistance Program for the drug within the preceding 1–year period; and

(2) (i) A 30–day supply of the maximum recommended dosage of the drug for any indication, according to the label for the drug approved under the Federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost;

(ii) A full course of treatment with the drug, according to the label for the drug approved under the Federal Food, Drug, and Cosmetic Act, would cost more than $80 at the drug's wholesale acquisition cost; or

(iii) If the drug is made available to consumers only in quantities that do not correspond to a 30–day supply, a full course of treatment, or a single dose, it would cost more than $80 at the drug's wholesale acquisition cost to obtain a 30–day supply or a full course of treatment.

(b) On request of the Attorney General, the manufacturer of an essential off–patent or generic drug identified in a notice under subsection (a) of this section, within 45 days after the request, shall submit a statement to the Attorney General:

(1) (i) Itemizing the components of the cost of producing the drug; and

(ii) Identifying the circumstances and timing of any increase in materials or manufacturing costs that caused any increase in the price of the drug within the 1–year period preceding the date of the price increase;

(2) (i) Identifying the circumstances and timing of any expenditures made by the manufacturer to expand access to the drug; and

(ii) Explaining any improvement in public health associated with those expenditures; and

(3) Providing any other information that the manufacturer believes to be relevant to a determination of whether a violation of this subtitle has occurred.

(c) The Attorney General may require a manufacturer or a wholesale distributor to produce any records or other documents that may be relevant to a determination of whether a violation of this subtitle has occurred.

(d) On petition of the Attorney General and subject to subsection (e) of this section, a circuit court may issue an order:

(1) Compelling a manufacturer or a wholesale distributor:

(i) To provide the statement required under subsection (b) of this section; and

(ii) To produce specific records or other documents requested by the Attorney General under subsection (c) of this section that may be relevant to a determination of whether a violation of this subtitle has occurred;

(2) Restraining or enjoining a violation of this subtitle;

(3) Restoring to any consumer, including a third party payor, any money acquired as a result of a price increase that violates this subtitle;

(4) Requiring a manufacturer that has engaged in price gouging in the sale of an essential off–patent or generic drug to make the drug available to participants in any State health plan or State health program for a period of up to 1 year at the price at which the drug was made available to participants in the State health plan or State health program immediately prior to the manufacturer's violation of this subtitle; and

(5) Imposing a civil penalty of up to $10,000 for each violation of this subtitle.

(e) The Attorney General may not bring an action for a remedy under subsection (d)(2) through (5) of this section unless the Attorney General has provided the manufacturer or wholesale distributor an opportunity to meet with the Attorney

General to offer a justification for the increase in the price of the essential off–patent or generic drug.

(f) Any information provided by a manufacturer or a wholesale distributor to the Attorney General under subsections (b) and (c) of this section shall be considered confidential commercial information for purposes of § 4–335 of the General Provisions Article unless the confidentiality of the information is waived by the manufacturer or wholesale distributor.

(g) In any action brought by the Attorney General under subsection (d) of this section, a person who is alleged to have violated a requirement of this subtitle may not assert as a defense that the person did not deal directly with a consumer residing in the State.

[Previous][Next]